

**REMARKS**

Reconsideration and withdrawal of the rejections of the application are respectfully requested in view of the remarks herein.

**I. STATUS OF THE CLAIMS AND FORMAL MATTERS**

Claims 1, 3-4, 6-17, 20-26, 28-32 and 35-42 are now pending. Claim 11 is amended and new claim 41 is added herein, without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents.

No new matter is added.

It is submitted that these claims are and were in full compliance with the requirements of 35 U.S.C §112. In addition, the amendment and remarks herein are not made for the purpose of patentability within the meaning of 35 U.S.C. §§101, 102, 103 or 112; but rather the amendments and remarks herein are made simply for clarification and to round out the scope of protection to which Applicants are entitled. Support for the amended claims is found throughout the specification.

**II. THE REJECTIONS UNDER 35 U.S.C. §112 ARE OVERCOME**

Claim 11 was rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particular point out and distinctly claim the subject matter of the invention. The rejection is respectfully traversed.

The Office Action stated that the phrase “epitope of interest” was unclear. The amendments to the claims herein have removed the phrase “of interest”. Accordingly, the rejection is now moot. Consequently, reconsideration and withdrawal of the rejection under 35 U.S.C. §112, second paragraph, is respectfully requested.

**III. THE DOUBLE PANTENTING REJECTIONS ARE OVERCOME**

Claims 1, 4, 6, 9-17, 20-26, 28-32 and 35-40 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-42 of copending Application Serial No. 10/346,021. And, claims 1, 4, 6, 9-17, 20-26, 28-32 and 35-40 were provisionally rejected under the judicially created doctrine of

obviousness-type double patenting as allegedly being unpatentable over claims 1-42 of copending Application Serial No. 10/116,963. The rejections are respectfully traversed.

As the double patenting rejections are only provisional, Applicants respectfully request that the rejections be held in abeyance until such time as a patent has issued or until such time as allowable subject matter has been found in both the present application and one of USSNs 10/116,963 and 10/346,021.

#### IV. THE ART REJECTIONS ARE OVERCOME

Claims 1, 4, 6, 9-17, 20-26, 28-32 and 35-40 were rejected under 35 U.S.C. §102(e) as allegedly being anticipated by Krieg *et al.* (U.S. Patent No. 6,339,068). The rejection is respectfully traversed.

The Office Action states that Krieg *et al.* teaches “vectors and methods for immunization”, including use of a bacterial vector, and that a gene gun may be used.

In contrast, the present application is directed towards methods of non-invasive immunization.

Notably, Krieg *et al.* used components purified from a bacterial vector, not the intact bacterial vector as the present application is directed.

Initially, it is respectfully submitted that for a Section 102 rejection to stand, the single prior art reference must contain all of the elements of the claimed invention, *see Lewmar Marine Inc. v. Barient Inc.*, 3 U.S.P.Q.2d 1766 (Fed. Cir. 1987), and, the single prior art reference must contain an enabling disclosure, *see Chester v. Miller*, 15 U.S.P.Q.2d 1333, 1336 (Fed. Cir. 1990).

Applying the law to the instant facts, in order for the rejection under Section 102(e) to be proper, Krieg *et al.* must teach a method of “non-invasive immunization” which comprises “contacting skin of the animal with a bacterial vector.” It is respectfully submitted that Krieg *et al.* does not teach such non-invasive immunization.

Rather, Krieg *et al.* states that “[p]lasmid DNA may be coated onto gold particles and introduced biolistically with a ‘gene-gun’ into the epidermis if [sic] the skin or the oral or vaginal mucosae”. Column 10, lines 54-57. As is explicitly stated in Krieg *et al.*, the use of a gene gun does not deliver the gene products onto the skin as is required by the present claims, but rather the gene gun deliver the gene products into the epidermis. Krieg *et al.* clearly shows an understanding of the method of use of a gene gun, namely that the gold particles are released

with such force that they **penetrate** the epidermis. Such a method, which involves **penetration** of the epidermis is **not** non-invasive, as is required by the present invention.

In fact, the use of a gene-gun is explicitly identified in the present specification as an invasive procedure, and is therefore explicitly outside the claim limitation of “non-invasive” when the term is read in light of the specification. For example, the Examiner is invited to review the specification at page 5, lines 18-20 wherein it is stated that “[c]urrent modes for the administration of genetic vaccines has focused on **invasive procedures** including needle injections, scarification, and gene gun-mediated penetration” (emphasis added).

Applicants respectfully submit that it is therefore clear that invasive procedures, including the use of a gene gun, are outside the scope of the presently claimed “non-invasive” immunization.

Further, attached as Exhibit 1 is an article from Cornell University entitled “Development of the ‘Gene Gun’ at Cornell”. This article describes the mechanism by which the gene gun works, and provides insight into the development of the device by Cornell University scientists and engineers.

The Examiner’s attention is respectfully drawn to page 2, 3<sup>rd</sup> paragraph, lines 7 and 8, wherein the gene gun is described as releasing particles which “penetrate the cells and release the DNA”. Although the gene gun was originally developed for use with plants, the technology has remained the same when used with humans and animals. Firing the gene gun results in the particles penetrating the targeted cells (which includes disrupting or penetrating the skin in the process).

Accordingly, the use of a gene gun is clearly not consistent with the non-invasive topical administration of the present invention, especially as the use of a gene gun is specifically identified in the present application as an example of invasive immunization and is therefore contrary to the claimed “non-invasive” immunization. Therefore, as Krieg *et al.* only teaches the use of a gene gun, and does not teach or suggest the non-invasive application of bacterial vectors to the skin, the rejection is improper and cannot stand. Reconsideration and withdrawal of the rejection under 35 U.S.C. §102(e) is respectfully requested.

**REQUEST FOR INTERVIEW**

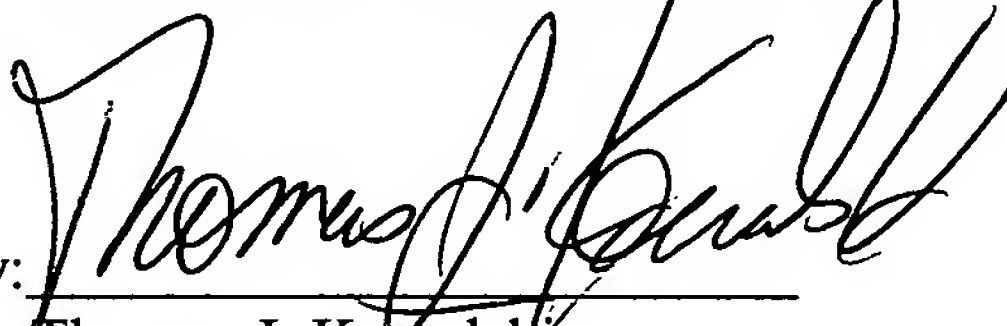
If any issue remains as an impediment to allowance, prior to issuance of any paper other than a Notice of Allowance, an interview, is respectfully requested, with the Examiner his supervisor, and, the Examiner is respectfully requested to contact the undersigned to arrange a mutually convenient time and manner for such an interview.

**CONCLUSION**

In view of the amendments, and remarks herein, the application is in condition for allowance. Reconsideration and withdrawal of the rejections of the application, and prompt issuance of a Notice of Allowance, is respectfully requested.

Respectfully submitted,

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